

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.
2. Claims 2, 4, 5, 9, 13, 15, 17, and 18 are cancelled. Claims 1, 3, 6-8, 10-12, 14, 16, and 19-27 are under examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Rejection of claims 1, 3, 6-8, 10-12, 14, 16, and 19-24 under 35 U.S.C. 103(a) as being unpatentable over US Patent 6017886 (Carnahan), in view of U.S. Patent 5367060, issued November 22, 1994 ('060) is maintained for reasons of record and hereby extended to include new claims 25-27. Applicant's arguments filed 07/02/2007 have been fully considered but they are not persuasive. Applicant first argues that in order to establish a prima facie case of obviousness, there must be 1) some suggestion or motivation in the art or in the knowledge

generally available to one of ordinary skill in the art, to modify or to combine the reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art references must teach or suggest all the claim limitations. This is not persuasive because the teaching-suggestion-motivation test is but one of several rationales that may support a conclusion of obviousness. The Supreme Court has reaffirmed principles based on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. at 82 USPQ2d at 1395. The rejection of record holds that Carnahan teaches activation of HER2/3 receptors in all of the target cell populations of the instant claims. The rejection of record also holds that the ‘060 patent teaches the boundaries of the EGF-like domains that are critical for activation of HER2/3 receptors, teaches the use of fragments that comprise the EGF-like domains, and teaches heregulin variants with changes at all specific residues and sites that are recited in instant claims 1, 3, 6-8, 10-12, 14, 16, and 19-24. The ‘060 patent specifically teaches that these are “Explanatory ([sic] exemplary?) substitutions common to any HRG” (paragraph bridging columns 22-23). Furthermore, the ‘060 patent teaches that positions corresponding to P213-E214 of SEQ ID NOs: 5, 7, and 9 (recited in new claim 25-27) differ among the various HRG classes and that residues at these are interchanged among HRG classes or EGF family members, are deleted, or a residue inserted adjacent hereto (column 23, lines 32-36) (The example cited refers to Q213-G215 of Hrg α , which corresponds to P213-E214 of other heregulins; see FIG. 6 of the instant specification and FIG. 9 in the ‘060 patent). Therefore, together with Carnahan, which teaches that several forms of heregulin are effective in stimulating utricular sensory epithelial cells, the ‘060 patent teaches that all of the instantly

claimed fragments and variants of Hrg are functionally interchangeable. Therefore, modifying the methods taught in Carnahan by using the Hrg fragments and variant taught in the '060 patent to arrive at the instantly claimed methods, is a matter of simple substitution of one known element for another to obtain predictable results.

Conclusion

5. No claims are allowed.
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 9717983 (Marchioni et al.), published 22 May, 1997, teaches that neuregulins (heregulins) that activate erbB related receptors affect inner ear cell mitogenesis (page 12, lines 1-10; page 20, lines 17-25; page 21, lines 1-15). Hair cells and support cells are taught as targets of neuregulin action (see claims 20-24).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG

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29 January 2008

/David S Romeo/

Primary Examiner, Art Unit 1647